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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/818,168

03/27/2001

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8271/85864

1917

22242 7590 05/18/2007
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EXAMINER

GOTTSCHALK, MARTIN A

ART UNIT

PAPER NUMBER

3694

MAIL DATE

DELIVERY MODE

05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/818,168

Applicant(s)

MUNOZ ET AL.

Examiner

Martin A. Gottschalk

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 22, 23 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 22, 23, and 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. Claims 1-7, 22, 23, and 26-33 are pending. Claims 1, 3, 22, 26, 28, and 29 are currently amended. Claims 1, 22, and 29 are independent. Claims 2, 4, 6, 7, 23, 27, and 30-33 have been previously presented. Claim five is as per the original. Claims 8-21, 24, and 25 have been, cancelled previously.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 22, and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection specifically refers to the nature and use of the claimed "information", and the first and second indicators of said information. See the following rejection under 35 USC § 112 second paragraph for more detail.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. The rejections applied to claims 26 in the previous Office Action is hereby withdrawn.

B. Claims 1-7 22, 23 and 26-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claims 1, 22, and 29 include language referring to the features of a first and second indicator of information. It is unclear from the claims how these indicators relate to each other, what result is intended to be obtained when using these indicators of information, and how they are intended to work together to obtain said result. For example, it is not clear how the fact that a first indicator has successfully identified correct information could be confirmed by audibly reciting a second indicator of the same information. Nor is it clear why, or to what end such a step should be performed. In addition, it is unclear what specific piece, or general type of "information" these two "indicator of information" features are intended to indicate vis a vis the claims. The remaining claims depend from these claims and are thus rejected as well.

Since these limitations provide no discernable additional meaning or functionality to the claims, for the purpose of examination no weight will be given to them.

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 3-5, 22, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobylevsky et al (US Pat# 6,493,427, hereinafter Kobylevsky) in view of Iliff (US Pat# 6,022,315, hereinafter Iliff).

A. As per claim 1, Kobylevsky discloses a method of processing a prescription refill request via an interactive voice response system (Kobylevsky: col 5, lns 5-67; col 6, lns 14-48), the method comprising the steps of:

(a) providing access for a pharmacy to the interactive voice response system (Kobylevsky: col 2, lns 53-56; Fig 1, note the arrows running between the Central

Pharmacy system and the Pharmacy) for obtaining approval of a refill request from a physician (Kobylevsky: col 6, Ins 30-35; col 7, Ins 32-42);

(b) prompting the pharmacy for a first indicator of information including at least one of:

prompting the pharmacy for a pharmacy identification (Kobylevsky: col 4, Ins 35-50; Fig 2, note the field marked 'Pharmacy Name'. The Examiner considers that pharmacy staff are among those who might be entering the name, and thus would be receiving the prompt.);

prompting the pharmacy for a patient identification;

and

prompting the pharmacy for identification of a medication corresponding to the prescription to be filled.

(c) in response to receiving the first indicator from the pharmacy, retrieving from a database a second indicator of the same information indicated by the first indicator and including at least one word, wherein the first indicator includes a different word or words than the word or words included in the second indicator,

wherein the words of the first and second indicators include letters or numbers or both letters and numbers; and (Kobylevsky: col 4, lns 51-58, i.e. the Examiner considers the imported voice file to be a second indicator related to the pharmacy name, the first indicator.);

Kobylevsky fails to explicitly disclose

(part of step b) wherein prompting for a first indicator of information includes audibly prompting by reciting a statement of words that describes the information;

However this feature is well known in the art as evidenced by the teachings of Iliff who discloses an interactive voice response system for obtaining and providing medical information (Iliff: abstract), and audibly prompting a user to provide information by reciting words to the user (e.g. Iliff: col 18, lns 44-47; col 29, lns 54-57).

Kobylevsky further fails to disclose the features of steps d and e, however these features are also taught by Iliff who teaches

(d) confirming, by the pharmacy, the first indicator identified the correct information by audibly reciting the second indicator of the information to the pharmacy with a statement of words including the words of the second indicator;

and

(e) requesting the user indicate whether or not the second indicator is correct (for steps e and d, see Iliff: col 13, lns 55-64).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kobylevsky and Iliff with the motivation of providing greater access to high quality, fast medical service at reasonable cost via a telephone network (Iliff: col 3, lns 7-15).

The same motivation applies to subsequent claims which combine the teachings of Kobylevsky and Iliff, is incorporated therein, and will not be repeated.

B. As per claim 3, Kobylevsky fails to explicitly disclose the features of this claim, however, these features are well known in the art as evidenced by Iliff who teaches the method of claim 1, further comprising at least one of:

the first indicator is a pharmacy phone number and the second indicator is the name of the pharmacy for confirming the pharmacy identification;

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the first indicator is at least a portion of a patient's name and the second indicator is a full name of the patient for confirming the patient identification (Iliff: col 29, Ins 54-57);

and

the first indicator is a NDC number and the second indicator is at least one of a generic name and a commercial name of the medication for confirming the medication.

C. As per claim 4, Kobylevsky discloses the method of claim 1, further comprising at least one of the steps of:

prompting for the date the prescription was last filled (Kobylevsky: col 7, Ins 57-61. The Examiner considers being required to enter the Rx number to be a form of prompting for the date the prescription was last filled, since the Rx number will have its date associated with it.);

prompting for the identification of the original prescribing physician (Kobylevsky: col 7, Ins 35-42, reads on "...state their full name and phone number...");

and

prompting for the quantity of the medication (Kobylevsky: col 7, Ins 40-42, reads on "... all relevant information for the...refill authorization..." Also col 7, Ins 57-61. The Examiner considers being required to enter the Rx number to be a form of prompting for the date the prescription was last filled, since the Rx number will have its date associated with it.).

D. As per claim 5, Kobylevsky discloses the method of claim 1, wherein

the prescription refill request is assigned a unique tracking identification (Kobylevsky: col 25, Ins 12-23. The Examiner considers the Rx number to be a unique tracking number)

Kobylevsky fails to disclose the rest of the features of this claim, however, this feature is taught by Iliff who teaches

wherein each response to a prompt is followed by a confirmation of the response (rejected as per the reasons provided for claim 3 above).

E. As per claim 26, Kobylevsky fails to explicitly disclose the features of this claim, however, these features are well known in the art as evidenced by the teachings of Iliff who discloses the method of claim 1, further comprising

prompting the pharmacy for a first indicator for each of a pharmacy identification, a patient identification, and an identification of a medication, wherein prompting for each first indicator includes audibly prompting the pharmacy.

F. As per claim 27, Kobylevsky discloses the method of claim 1, further including the steps of

responding to the prompting steps by using a keypad on a telecommunication device (Kobylevsky: col 6, Ins 44-47).

G. As per claim 28, the method of claim 1, further comprising the step of

permitting the pharmacy to obtain refill information through the interactive voice response system only if the second indicator is correct.

H. Claim 22 is a system claim which substantially repeats the limitations of claim 1, the corresponding method claim, thus claim 22 is rejected for the same reasons as claim 1.

8. Claims 2, 6, 7, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobylevsky in view of Iliff as applied to claim 1 above, and further in view of Goetz et al (US Pat# 6,421,650, hereinafter Goetz).

A. As per claim 2, Kobylevsky discloses the method of claim 1, further comprising the step of

providing an authorization for the requested refill (Kobylevsky: col 7, lns 39-42; col 29, lns 9-22).

Kobylevsky fails to disclose

displaying both a NDC number and the name of the medication to a physician for the requested refill.

However, this feature is well known in the art as evidenced by the teachings of Goetz.

Goetz teaches a health care provider inputting a NDC number corresponding to the prescription to be filled to supply necessary information about the medication to the patient (Goetz: col 6, lns 1-19), and the NDC number being used in physician software to display information about drug interactions (Goetz: col 12, lns 51-53; Fig 44, items 206 and 212). The drug name is displayed along with the interaction warning (Goetz:

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fig 23) for the physician to provide authorization for the prescription (Fig 24). It is logical that the physician component, merely as a matter of design choice, could also display the NDC number, acquired from the database providing the information shown in Fig 44.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the teachings of Goetz within the method of Kobylevsky in order to provide patients easy access to complete medical information on a prescription (Goetz: col 1, Ins 64-67).

B. As per claim 6, Kobylevsky discloses the method of claim 1, further comprising the steps of:

creating a database entry for each prescription refill request (Kobylevsky: col 24, Ins 6-20 and 59-61),

However, Kobylevsky fails to explicitly disclose the method of claim 1, where the database entry for each prescription refill includes:

a NDC identification and a corresponding commercial or generic name

of the medication corresponding to the NDC identification, whereby a physician or individual may consider and provide the refill authorization based on the commercial or generic name of the medication.

However, these features are well known in the art as evidenced by the teachings of Goetz.

Goetz teaches a relational database which includes drug names and their corresponding NDC numbers (Goetz: col 15, lns 32-37; Fig 44, note in particular the fields labeled "Drug" and "NDC"). Fig 44, item 212 in particular shows a step where a physician or individual might consider this information.

The motivation to combine the teachings of Goetz within the method of Kobylevsky are the same as provided for claim 2 and is incorporated herein.

C. As per claim 7, Kobylevsky discloses the method of claim 6, further comprising at least one of the steps of:

providing a physician or other user access to the database entry (Kobylevsky: col 29, lns 18-31);

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prompting the physician or other user for the confirmation that the requested prescription is compatible with other medications, if any, prescribed to the patient;

prompting the physician or other user to enter comments (Kobylevsky: col 7, Ins 42-45);

prompting the physician or other user to indicate approval of the request (Kobylevsky: col 7, Ins 36-42, reads on "...prompted by the system to <provide> refill authorization.);

and

prompting the physician or other user to dispatch the indication of approval and corresponding comments, if any, to the requesting pharmacy (same reasons as provided above for the two "prompting..." steps.

D. Claim 23 is a system claim which substantially repeats the limitations of claim 6, the corresponding method claim, thus claim 23 is rejected for the same reasons as claim 6.

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9. Claims 29 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobylevsky in view of Goetz.

A. As per claim 29, Kobylevsky discloses a method of processing a prescription refill request comprising the steps of:

(a) audibly prompting a pharmacy (Kobylevsky: col 6, Ins 49-52) by a statement of words requesting a first indicator of information related to the refill request (Kobylevsky: col 14, Ins 32-38, first indicator is the Rx number);

(b) providing first indicator by using a keypad on a telecommunication device (Kobylevsky: col 16, Ins 34-42, i.e. the keyboard can be used to navigate and enter information);

(c) in response to receiving the first indicator from the pharmacy, using the first indicator to look up the information (Kobylevsky: col 14, Ins 32-38, first indicator is the Rx number, looks up refill information);

(d) retrieving a second indicator of the same information indicated by the first indicator and that includes different word or words from a word or words included in the first indicator of the information, wherein the words include letters, numbers or both (Kobylevsky: col 14, Ins 32-38, second indicator is the phone number);

(e) confirming, by the pharmacy, the first indicator identifies the correct information by providing the pharmacy with an audible statement of words reciting the second indicator of the information (Kobylevsky: col 25, Ins 21-23), and answering whether or not the audible statement reciting the second indicator is correct by using a keypad (Kobylevsky: col 25, Ins 19-21);

Kobylevsky fails to disclose the remaining feature of this claim, however, this feature is well known in the art as evidenced by the teachings of Goetz who discloses

(g) displaying the information to a physician required to approve or deny the refill request (Goetz: col 12, Ins 32-50. The passage teaches a prescribing physician reviewing – i.e. displaying via the “physician’s component” – patient compliance with a treatment regimen approved by the physician.).

The motivation to combine the teachings of Kobylevsky and Goetz are the same as provided for claim 2 above and are incorporated herein.

B. As per claim 33, it recites the method of claim 29 wherein

both a NDC number and the name of the medication is displayed to the physician (rejected as per the reasons provided for the same limitation recited in claim 2 above).

10. Claims 30-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Kobylevsky in view of Goetz as applied to claim 29 above and further in view of Pilarczyk (US Pat# 4,766,542).

A. As per claims 30-32, Kobylevsky and Goetz disclose methods and systems comprising databases which further comprise complete information regarding a pharmacy, a patient, and a prescription, such information comprising for example:

(claim 30) the pharmacy's phone number

and

the name of the pharmacy (for both features, see Kobylevsky: col 23, Ins 15-39; Fig 2, the field labeled "Pharmacy Name");

(claim 31) the patient's full name (Kobylevsky: col 7, Ins 39-42; col 20, Ins 31-32);

(claim 32) the NDC number for the medication (Goetz: col 15, Ins 32-37)

and

the name of the medication being prescribed (e.g. Goetz: Fig 21, i.e. "Canderill").

Kobylevsky and Goetz fail to explicitly teach accessing such information in a database and converting it into an audible message. However, this feature is well known in the art as evidenced by the teachings of Pilarczyk. Pilarczyk teaches a method and system incorporating a speech synthesizer that takes as input prescription-related information (Pilarczyk: col 1, ln 67 to col 2, ln 2; Fig 1, item 18) so as to provide audible output regarding refill information (Pilarczyk: col 3, lns 56-67). Pilarczyk further teaches that commercially available speech synthesis systems are old and well known (Pilarczyk: col 4, ln 46 to col 5, ln 15), and describes in detail the operation of such a system (Pilarczyk: col 7, ln 40 to col 9, lns 68).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the teachings of Pilarczyk with the collective teachings of Kobylevsky and Goetz with the motivation of providing greater assurance a patient obtains the full prescribed number of doses of a drug, encouraging greater patient compliance with a prescription regimen, and promoting increased return business to a pharmacy from a patient (Pilarczyk: col 1, lns 14-50).

Response to Arguments

11. On pages 8-11 of the response filed 12/07/2006, Applicant provides a plurality of arguments essentially directed to the features referred to and rejected in the sections above concerning 35 USC § 112 first and second paragraphs. Due to the lack of clarity of these features, Applicant's arguments that these claim amendments overcome the prior art rejections applied in the previous Office Action are found to be non-persuasive.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

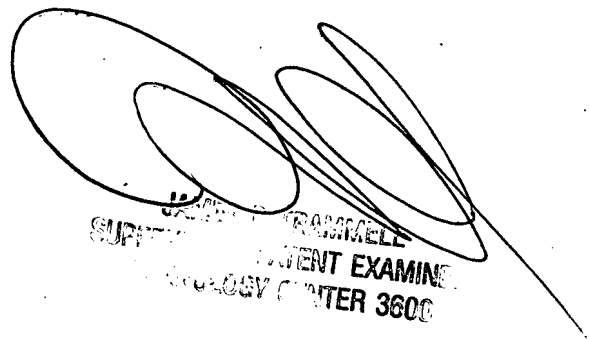
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin A. Gottschalk whose telephone number is (571) 272-7030. The examiner can normally be reached on Mon - Fri 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James P. Trammell can be reached on (571) 272-6712. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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